General

Guideline Title

Pirfenidone for treating idiopathic pulmonary fibrosis.

Bibliographic Source(s)

National Institute for Health and Care Excellence (NICE). Pirfenidone for treating idiopathic pulmonary fibrosis. London (UK): National Institute for Health and Care Excellence (NICE); 2013 Apr. 66 p. (Technology appraisal guidance; no. 282).

Guideline Status

This is the current release of the guideline.

Recommendations

Major Recommendations

Pirfenidone is recommended as an option for treating idiopathic pulmonary fibrosis only if:

- The person has a forced vital capacity (FVC) between 50% and 80% predicted and
- The manufacturer provides pirfenidone with the discount agreed in the patient access scheme.

Treatment with pirfenidone that is recommended according to the first recommendation above should be discontinued if there is evidence of disease progression (a decline in per cent predicted FVC of 10% or more within any 12 month period).

People currently receiving pirfenidone that is not recommended according to the first recommendation above should have the option to continue treatment until they and their clinician consider it appropriate to stop.

Clinical Algorithm(s)

A National Institute for Health and Care Excellence (NICE) pathway for idiopathic pulmonary fibrosis is available on the NICE Web site .

Scope

Disease/Condition(s)

Idiopathic pulmonary fibrosis

Guideline Category

Assessment of Therapeutic Effectiveness

Treatment

Clinical Specialty

Family Practice

Internal Medicine

Pulmonary Medicine

Intended Users

Advanced Practice Nurses

Nurses

Physician Assistants

Physicians

Respiratory Care Practitioners

Guideline Objective(s)

To determine the clinical effectiveness and cost-effectiveness of pirfenidone for treating idiopathic pulmonary fibrosis

Target Population

People with mild to moderate idiopathic pulmonary fibrosis

Interventions and Practices Considered

Pirfenidone

Major Outcomes Considered

- Disease activity
- Physical function
- Worsening of disease
- Mortality
- Fatigue
- Adverse effects of treatment
- Health-related quality of life
- Adverse effects
- Cost-effectiveness

Methodology

Methods Used to Collect/Select the Evidence

Hand-searches of Published Literature (Primary Sources)

Hand-searches of Published Literature (Secondary Sources)

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

Note from the National Guideline Clearinghouse (NGC): The National Institute for Health and Care Excellence (NICE) commissioned an independent academic centre to perform a systematic literature review on the technology considered in this appraisal and prepare an Evidence Review Group (ERG) report. The ERG report for this appraisal was prepared by the Southampton Health Technology Assessments Centre (see the "Availability of Companion Documents" field).

Clinical Effectiveness

Critique of Manufacturer's Approach to Systematic Review

Description of Manufacturer's Search Strategy for Clinical Effectiveness

The manufacturer's literature searches for clinical effectiveness were checked by an information scientist and are considered to be reasonably comprehensive, fit for purpose and reproducible. The narrative description of the approach to the literature searches is good. The documentation of the search strategies contain a balance of descriptor and free text terms with adequate truncation, mapping to subject headings, correctly linked sets and comprising acceptable randomised controlled trial (RCT), non-RCT, adverse event, quality of life, and cost search filters.

Supplementary searching of in-house company databases and reference checking is also recorded by the manufacturer. Multi-file cross searching was undertaken rather than searching the databases separately. This results in some repetition in the indirect mixed treatment comparisons search section but this is unlikely to affect the results.

The ERG ran additional searches on Medline, Medline In Process (MEIP) and Embase to establish whether there were any further RCTs for triple therapy (prednisolone, azathioprine, N-acetylcysteine) of relevance.

The manufacturer's submission (MS) makes reference to on-going trials from the ClinicalTrials.gov database; however, no overt documentation of a strategy or sources used to identify these trials was identified in the MS. The ERG ran searches on controlled-trials.com and UK Clinical Research Network (UKCRN) Portfolio Data checking for further on-going trials data.

Statement of the Inclusion/Exclusion Criteria Used in the Study Selection

To be included in the systematic review, trials had to meet the eligibility criteria that were provided in the MS. There are some differences between the criteria in the MS, those of the decision problem, and the licensed indication:

- The population described in the final scope (NICE), the decision problem in the submission and the licensed indication for pirfenidone the population is restricted to people with mild to moderate idiopathic pulmonary fibrosis (IPF). The eligibility criteria for the MS systematic review are stated as people with IPF.
- The comparator was not used to determine eligibility for the systematic review.
- The total maximum daily dose of pirfenidone recommended in the licensed indication is 2,403 mg/day but dose is not noted in the NICE scope, the decision problem addressed, or the inclusion criteria.
- Study design was provided as an inclusion criterion for the MS systematic review (limited to RCTs with open label extensions with parallel design, or comparing different doses or schedules of the drug also considered). It is not usual to state study design in the decision problem.

No limits were placed on inclusion criteria relating to the quality of RCTs (both blinded and non-blinded RCTs eligible) or other study types.

Refer to Section 3 of the ERG Report for additional detail on the manufacturer's search strategy for clinical effectiveness.

Economic Evaluation

Overview of Manufacturer's Economic Evaluation

The manufacturer's submission to NICE includes:

i. A review of published economic evaluations of pirfenidone for the treatment of IPF
ii. A report of an economic evaluation undertaken for the NICE Single Technology Appraisal (STA) process. The cost-effectiveness of pirfenidone is compared with best supportive care for adult patients with mild to moderate IPF

Manufacturer's Review of Published Economic Evaluations

A systematic search of the literature was conducted by the manufacturer to identify economic evaluations of pirfenidone for the treatment of IPF. The inclusion and exclusion criteria for the systematic review are listed in the MS. The inclusion criteria state that cost-effectiveness or cost studies of adults with suspected or diagnosed IPF would be included. Studies considered to be methodologically unsound, lacking adequate detail or devoid of any costing analysis were excluded.

Critical Appraisal of the Manufacturer's Submitted Economic Evaluation

Three studies were identified from screening 205 titles and abstracts. Of these all three studies were excluded. Two were costing studies and the other study was a cost-effectiveness analysis for IPF but not for the use of pirfenidone treatment.

The ERG checked the search strategy used for the cost-effectiveness searches and considered them reasonably comprehensive, fit for purpose, and reproducible. An additional search of National Health Service Economic Evaluation Database (NHSEED) has been run by the ERG and has not found any cost-effectiveness studies for pirfenidone.

Number of Source Documents

Clinical Effectiveness

26 studies met the inclusion criteria.

Economic Analysis

- All three identified studies were excluded
- The manufacturer submitted an economic evaluation

Methods Used to Assess the Quality and Strength of the Evidence

Expert Consensus

Rating Scheme for the Strength of the Evidence

Not applicable

Methods Used to Analyze the Evidence

Meta-Analysis

Review of Published Meta-Analyses

Systematic Review with Evidence Tables

Description of the Methods Used to Analyze the Evidence

Note from the National Guideline Clearinghouse (NGC): The National Institute for Health and Care Excellence (NICE) commissioned an independent academic centre to perform a systematic literature review on the technology considered in this appraisal and prepare an Evidence Review Group (ERG) report. The ERG report for this technology appraisal was prepared by the Southampton Health Technology Assessments

Centre (see the "Availability of Companion Documents" field).

Clinical Effectiveness

Table 1 in the ERG report provides a summary of key features of included randomised controlled trials.

Description and Critique of the Approach to Validity Assessment

The manufacturer's submission (MS) quality assessed the included trials using the NICE criteria and presents a summary in Table 2 in the ERG report, with further detail available in MS Appendix 3.

See Section 3.1.4 in the ERG report for additional detail on validity assessment.

Description and Critique of Manufacturer's Outcome Selection

The outcomes selected by the manufacturer seem appropriate and match the NICE scope/decision problem.

See Section 3.1.5 in the ERG report for additional detail on outcome selection.

Description and Critique of the Manufacturer's Approach to Trial Statistics

The MS reports trial results for the relevant outcome measures. The units of measurement, size of effect, numbers in analysis and whether an intention to treat (ITT) analysis or not plus a discussion/justification of clinically important differences are reported for the majority of outcomes. The 95% confidence intervals (CI) (or an alternative such as standard deviations [SDs]), however, are frequently not reported, particularly for mean % change outcomes. The 95% CIs are reported for hazard ratios and some SDs are reported for the mean % change outcomes from SP3. In a few cases SDs which are reported in a trial publication are not reported in the MS. The MS discusses the definition for a 'treatment adherent population'; however, the ERG was not able to identify any outcome data presented for the treatment adherent population.

Some interim data on adverse events are reported for the ongoing non-randomised studies RECAP (PIPF-012) and PIPF-002. It is clear in the MS that these data are from interim analyses.

Description and Critique of the Manufacturer's Approach to the Evidence Synthesis

A narrative review of evidence is provided in the MS, together with an overview of two published meta-analyses. In general the tabulated data and the narrative data presented in the MS reflect the data presented in the trial publications. In the summary of outcomes (see Section 3.3 in the ERG report) the ERG note any issues identified on checking the data.

For the CAPACITY trials the MS presents data for each trial separately and for an *apriori* pooled analysis. The pooled analyses were also presented in the trial publication. In a response to a request for clarification over the methods used for the pooled analysis, the manufacturer provided the rationale and detailed methods for these analyses. No discussion has been given in the MS of the rationale for having two separate trials however.

Various meta-analyses are provided. These generally combined outcomes in two ways:

1. Data from three studies (CAPACITY 2; CAPACITY 1; and SP3)
2. Data from two studies (CAPACITY 2; CAPACITY 1) as the MS states that these were used for the cost-effectiveness model.

The CAPACITY 1 and CAPACITY 2 studies were very similar and are therefore appropriate for meta-analysis. The SP2 and SP3 studies were undertaken in Japanese participants and the dose of pirfenidone used was different from the CAPACITY trials. However, these doses should be largely comparable because of the different mean weight of the populations involved (the dose in the UK licensed indication was calculated by the manufacturer after adjusting the doses used in the Japanese studies to account for greater mean weight). One of the previously published meta-analyses included all four studies. However, the manufacturer has not undertaken meta-analyses including the SP2 study with the exception of the analysis of mortality. No explanation has been provided by the MS for not including SP2 although the ERG assumes this was related to the difference in the length of follow-up.

Outcomes pooled were change in forced vital capacity/vital capacity (FVC/VC) (the MS also included a meta-analysis of CAPACITY 2 and SP3 as a 'low-dose' comparison); change in 6-minute walk test; progression-free survival; mortality (CAPACITY 1; CAPACITY 2; SP3 and SP2 combined); quality of life and adverse effects. Other outcomes (dyspnoea and worst SpO_2) were meta-analysed with data presented in Appendix 21 of the MS.

See section 3.1.7 of the ERG report for additional information on evidence synthesis.

See the Addendum to the ERG report (see the "Availability of Companion Documents" field) for an overview of the Manufacturer's additional analyses on clinical effectiveness.

Economic Evaluation

The cost-effectiveness analysis uses a micro-simulation model to estimate the cost-effectiveness of pirfenidone compared with best supportive care in adult patients with mild to moderate idiopathic pulmonary fibrosis (IPF). The model adopted a lifetime horizon in order to capture the differential effect of the interventions on patients' survival, with a 24-week cycle length. Although triple therapy with prednisolone, azathioprine, and N-acetylcysteine was scoped as a relevant comparator, the MS does not present a cost-effectiveness analysis of pirfenidone compared to triple therapy.

The economic evaluation uses pooled data from the CAPACITY trials and assumes that the trial patient population is representative of the UK population that is likely to receive pirfenidone. The MS also presents subgroup analysis for patients with a % predicted FVC of <80% in the CAPACITY trials, as these were reported to experience a greater treatment effect in the clinical trials.

A Markov-type structure was used to model the progression of patients through six health states: *Alive and hospitalised, Alive not hospitalised, Dead due to IPF-related causes and hospitalised, Dead due to IPF-related causes not hospitalised, Dead due to other causes and hospitalised, and Dead due to other causes not hospitalised.*

Refer to Section 4 of the ERG report for more information on cost-effectiveness analysis. See the Addendum to the ERG report for an overview of the Manufacturer's additional economic analyses.

Methods Used to Formulate the Recommendations

Expert Consensus

Description of Methods Used to Formulate the Recommendations

Technology appraisal recommendations are based on a review of clinical and economic evidence.

Technology Appraisal Process

The National Institute for Health and Care Excellence (NICE) invites 'consultee' and 'commentator' organisations to take part in the appraisal process. Consultee organisations include national groups representing patients and carers, the bodies representing health professionals, and the manufacturers of the technology under review. Consultees are invited to submit evidence during the appraisal and to comment on the appraisal documents.

Commentator organisations include manufacturers of the products with which the technology is being compared, the National Health Service (NHS) Quality Improvement Scotland and research groups working in the area. They can comment on the evidence and other documents but are not asked to submit evidence themselves.

NICE then commissions an independent academic centre to review published evidence on the technology and prepare an 'assessment report'. Consultees and commentators are invited to comment on the report. The assessment report and the comments on it are then drawn together in a document called the evaluation report.

An independent Appraisal Committee then considers the evaluation report. It holds a meeting where it hears direct, spoken evidence from nominated clinical experts, patients and carers. The Committee uses all the evidence to make its first recommendations, in a document called the 'appraisal consultation document' (ACD). NICE sends all the consultees and commentators a copy of this document and posts it on the NICE Web site. Further comments are invited from everyone taking part.

When the Committee meets again it considers any comments submitted on the ACD; then it prepares its final recommendations in a document called the 'final appraisal determination' (FAD). This is submitted to NICE for approval.

Consultees have a chance to appeal against the final recommendations in the FAD. If there are no appeals, the final recommendations become the basis of the guidance that NICE issues.

Who Is on the Appraisal Committee?

NICE technology appraisal recommendations are prepared by an independent committee. This includes health professionals working in the NHS and people who are familiar with the issues affecting patients, and carers. Although the Appraisal Committee seeks the views of organisations representing health professionals, patients, carers, manufacturers and government, its advice is independent of any vested interests.

Rating Scheme for the Strength of the Recommendations

Not applicable

Cost Analysis

Summary of Appraisal Committee's Key Conclusions on the Manufacturer's Economic Model

Availability and Nature of Evidence

The Committee had reservations over the complexity and lack of transparency of the manufacturer's microsimulation model. The Committee concluded that the outlined structure of the model adhered to the National Institute for Health and Care Excellence (NICE) reference case for economic analysis and was acceptable for assessing the cost-effectiveness of pirfenidone.

Uncertainties Around and Plausibility of Assumptions and Inputs in the Economic Model

The Committee expressed doubts over the methods used by the manufacturer in subsequently calibrating the model to ensure mortality matched that at 72 weeks in PIPF-004 and PIPF-006 and was concerned that the manufacturer assumed that the treatment effect then persisted until death, although limited evidence for efficacy beyond 72 weeks, had been presented in its submission. It also had some reservations about the costs used and how quality of life had been indirectly incorporated into the model rather than using trial data. The Committee concluded that there was some uncertainty in several inputs in the model.

Incorporation of Health-Related Quality-of-Life Benefits and Utility Values. Have Any Potential Significant and Substantial Health-Related Benefits Been Identified That Were Not Included in the Economic Model, and How Have They Been Considered?

The Committee had some reservations about how quality of life had been indirectly incorporated into the model rather than using trial data. It noted that uncertainty had been added in estimating health effects when predicting the St George's Respiratory Questionnaire score using age, gender, forced vital capacity (FVC), and 6-minute walk test distance and then when mapping the St George's Respiratory Questionnaire to the European QoL 5 dimensions (EQ-5D). The Committee concluded that there was some uncertainty in the estimation of utilities using the manufacturer's model, but that the estimates were adequate for decision-making.

Are There Specific Groups of People for Whom the Technology Is Particularly Cost-Effective?

The Committee was persuaded that the subgroup results from patients with FVC 80% predicted or could be used to inform treatment decisions in UK clinical practice, and that this was the most appropriate population for evaluation. It noted that the manufacturer's probabilistic incremental cost-effectiveness ratio (ICER) was £24,000 per quality-adjusted life year (QALY) gained, which was less than the Evidence Review Group's (ERG) deterministic ICER for the mild-to-moderate population (the value is confidential).

What Are the Key Drivers of Cost-Effectiveness?

The Committee discussed how uncertainty in the manufacturer's model had been explored in univariate sensitivity analyses by the manufacturer and the ERG. The Committee agreed with the manufacturer's conclusion that the ICERs were also sensitive to the discount rates for costs and outcomes as well as the daily dosage of pirfenidone. The Committee concluded that there was some uncertainty associated with the estimates of treatment effect of pirfenidone and mortality related to idiopathic pulmonary fibrosis, but that the level of uncertainty was acceptable for decision-making.

Most Likely Cost-Effectiveness Estimate (Given as an ICER)

The Committee was persuaded that the subgroup results from patients with FVC 80% predicted or less was the most appropriate population for evaluation. It considered that triple therapy was no longer routine or best practice in the National Health Service for patients starting treatment for idiopathic pulmonary fibrosis, and so best supportive care should be considered the sole comparator for pirfenidone.

The Committee therefore agreed that the most plausible ICER was for the comparison of pirfenidone with best supportive care in people who had idiopathic pulmonary fibrosis with FVC 80% predicted or less, incorporating the second patient access scheme. It noted that the manufacturer's

probabilistic ICER was £24,000 per QALY gained. It concluded that this offered an acceptable cost-effectiveness estimate on which to begin to explore its further considerations.

Method of Guideline Validation

External Peer Review

Description of Method of Guideline Validation

Consultee organisations from the following groups were invited to comment on the draft scope, Assessment Report and the Appraisal Consultation Document (ACD) and were provided with the opportunity to appeal against the Final Appraisal Determination.

- Manufacturer/sponsors
- Professional/specialist and patient/carer groups
- Commentator organisations (without the right of appeal)

In addition, individuals selected from clinical expert and patient advocate nominations from the professional/specialist and patient/carer groups were also invited to comment on the ACD.

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

The type of evidence supporting the recommendations is not specifically stated.

The Appraisal Committee considered clinical and cost-effectiveness evidence submitted by the manufacturer of pirfenidone and a review of this submission by the Evidence Review Group. For clinical effectiveness, 4 randomised controlled studies and 2 open-label studies were considered. For cost-effectiveness, an economic evaluation was undertaken.

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

Appropriate use of pirfenidone for treating idiopathic pulmonary fibrosis

Potential Harms

The summary of product characteristics lists the following adverse reactions for pirfenidone as the most commonly reported (10% or higher): nausea, rash, fatigue, diarrhoea, dyspepsia, and photosensitivity reaction.

For full details of adverse reactions and contraindications, see the summary of product characteristics available at http://emc.medicines.org.uk/ .

Qualifying Statements

Qualifying Statements

- This guidance represents the views of the National Institute for Health and Care Excellence (NICE) and was arrived at after careful consideration of the evidence available. Healthcare professionals are expected to take it fully into account when exercising their clinical

judgement. However, the guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

- Implementation of this guidance is the responsibility of local commissioners and/or providers. Commissioners and providers are reminded that it is their responsibility to implement the guidance, in their local context, in light of their duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity and foster good relations. Nothing in this guidance should be interpreted in a way that would be inconsistent with compliance with those duties.

Implementation of the Guideline

Description of Implementation Strategy

Section 7(6) of the National Institute for Health and Care Excellence (NICE) (Constitution and Functions) and the Health and Social Care Information Centre (Functions) Regulations 2013 requires clinical commissioning groups, Nation Health Service (NHS) England and, with respect to their public health functions, local authorities to comply with the recommendations in this appraisal within 3 months of its date of publication.

When NICE recommends a treatment 'as an option', the National Health Service (NHS) must make sure it is available within the period set out in the paragraph above. This means that, if a patient has idiopathic pulmonary fibrosis and the doctor responsible for their care thinks that pirfenidone is the right treatment, it should be available for use, in line with NICE's recommendations.

The Department of Health and the manufacturer have agreed that pirfenidone will be available to the NHS with a patient access scheme which makes pirfenidone available with a discount. The size of the discount is commercial in confidence. It is the responsibility of the manufacturer to communicate details of the discount to the relevant NHS organisations. Any enquiries from NHS organisations about the patient access scheme should be directed to Shrikesh Shah – Senior Director, Finance UK and Ireland, InterMune (+44 [0] 203 589 2760).

NICE has developed tools to help organisations put this guidance into practice (listed below). These are available on the NICE Web site (see also the "Availability of Companion Documents" field).

- Costing template and report to estimate the national and local savings and costs associated with implementation

Implementation Tools

Clinical Algorithm

Patient Resources

Resources

For information about availability, see the *Availability of Companion Documents* and *Patient Resources* fields below.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Getting Better

Living with Illness

IOM Domain

Effectiveness

Identifying Information and Availability

Bibliographic Source(s)

National Institute for Health and Care Excellence (NICE). Pirfenidone for treating idiopathic pulmonary fibrosis. London (UK): National Institute for Health and Care Excellence (NICE); 2013 Apr. 66 p. (Technology appraisal guidance; no. 282).

Adaptation

Not applicable: The guideline was not adapted from another source.

Date Released

2013 Apr

Guideline Developer(s)

National Institute for Health and Care Excellence (NICE) - National Government Agency [Non-U.S.]

Source(s) of Funding

National Institute for Health and Care Excellence (NICE)

Guideline Committee

Appraisal Committee

Composition of Group That Authored the Guideline

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Financial Disclosures/Conflicts of Interest

Committee members are asked to declare any interests in the technology to be appraised. If it is considered there is a conflict of interest, the member is excluded from participating further in that appraisal.

Guideline Status

This is the current release of the guideline.

Guideline Availability

Electronic copies: Available from the National Institute for Health and Care Excellence (NICE) Web site .

Availability of Companion Documents

The following are available:

- Pirfenidone for the treatment of idiopathic pulmonary fibrosis. Costing template. London (UK): National Institute for Health and Care Excellence (NICE); 2013 Apr. (Technology appraisal 282). Electronic copies: Available from the National Institute for Health and Care Excellence (NICE) Web site .
- Pirfenidone for the treatment of idiopathic pulmonary fibrosis. Evidence Review Group (ERG) report. National Southampton Health Technology Assessments Centre; 2012 Sep. 80 p. Electronic copies: Available from the NICE Web site .
- Pirfenidone for the treatment of idiopathic pulmonary fibrosis: ERG overview of manufacturer's additional analyses and Patient Access Scheme (PAS). Evidence Review Group report addendum. National Southampton Health Technology Assessments Centre; 2012 Sep. 19 p. Electronic copies: Available from the NICE Web site .
- Idiopathic pulmonary fibrosis overview. NICE pathway. London (UK): National Institute for Health and Care Excellence (NICE); 2013 Jun. (Technology appraisal; no. 282). Electronic copies: Available from the NICE Web site .

Patient Resources

The following is available:

- Pirfenidone for idiopathic pulmonary fibrosis. Information for the public (Technology Assessment 282). London (UK): National Institute for Health and Care Excellence (NICE); 2013 Apr. 6 p. (Technology Assessment 282). Electronic copies: Available from the National Institute for Health and Care Excellence (NICE) Web site . Also available in Welsh from the NICE Web site .

Please note: This patient information is intended to provide health professionals with information to share with their patients to help them better understand their health and their diagnosed disorders. By providing access to this patient information, it is not the intention of NGC to provide specific medical advice for particular patients. Rather we urge patients and their representatives to review this material and then to consult with a licensed health professional for evaluation of treatment options suitable for them as well as for diagnosis and answers to their personal medical questions. This patient information has been derived and prepared from a guideline for health care professionals included on NGC by the authors or publishers of that original guideline. The patient information is not reviewed by NGC to establish whether or not it accurately reflects the original guideline's content.

NGC Status

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